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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|-----------------------|-------------------------|------------------|
| 09/684,064   | 10/06/2000  | Gordon Ian Rowlandson | 39199-9511-00           | 2853             |
| 7590   | 05/06/2004  |                       | EXAMINER                |                  |
| Thomas A. Miller<br>Michael Best & Friedrich LLP<br>Suite 3300<br>100 East Wisconsin Avenue<br>Milwaukee, WI 53202 |             |                       | BUI, KIM T              |                  |
|  |             |                       | ART UNIT                | PAPER NUMBER     |
|  |             |                       | 3626                    |                  |
|  |             |                       | DATE MAILED: 05/06/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                        |
|------------------------------|------------------------|------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>    |
|                              | 09/684,064             | ROWLANDSON, GORDON IAN |
|                              | <b>Examiner</b>        | <b>Art Unit</b>        |
|                              | Kim T. Bui             | 3626                   |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 15 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4&amp;5</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Specification***

1. The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 24, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (A) In claim 7, "some of" on line 3 is vague;
- (B) In claim 24, "the integrity of the physiological data" on line 2 lacks clear antecedent basis;
- (C) In claims 30, "the integrity of the acquired physiological data" on line 2 lacks clear antecedent basis.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6,8-17,19-21,23-31 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Mardirossian (6011991) in view of Selvester et al (6230048).

(A) As per claim 1, Mardiorossian discloses real time support system and method for monitoring physiological data, comprising the steps for:

a. establishing a library of interpreted physiological data records (i.e., memory 57 for storing a plurality of files or patterns of measured brain activity or responses of particular individuals) (Mardirossian, col. 2, lines 26-31, col. 5, lines 27-31, lines 37-44);

b. gathering sensed physiological signal (Maridirossian, col. 3, lines 41-43, col. 6, lines 34-42);

c. interpreting the sensed physiological signal according to predefined criteria to generate an interpretation (Mardirossian, col. 3, lines 46-47, col. 6, lines 63 to col. 7, line 15, col. 5, line 58 to col. 6, lines 29);

d. correlating (i.e. comparing) the interpretation with the physiological data records (Mardirossian, col. 2, lines 32-35, col. 3, lines 22-23, lines 50-53).

Mardirossian fails to explicitly recite the step for displaying the interpretation and the correlated physiological records on a display. This, however, is disclosed by Selvester et al. Selvester et al. teaches a pictorial display electrocardiographic interpretation system wherein interpretation, predictive interpretation, interpretation at different times T1, T2, etc.. can be presented in static or motion display (Selvester et al, col. 3, lines 17-33, lines 59-65, col. 4, lines 14-23,Figs. 2, 6 a, 6b, 7a,7b, 11a-c,12 a-b,13 a-b,124a-b, 15 a-b). It would have been obvious to one having ordinary skill in the

art at the time of the invention to include pictorial display system of Selvester et al. into Mardirossian with the motivation of providing a better representational output display with high degree of configurational and other accuracy of certain selected heart conditions. (Selvester et al. col. 1, lines 19- 25, col. 3, lines 60-65).

(B) As per claim 2, Maridossian and Selvester teach the communication link to an expert location in col. 2, lines 54-56, col. 3, lines 47-49 of Maridossian, and col.10, lines 47-54,col. 15, lines 1-9, Fig. 3 of Selvester et al.

(C) As per claims 3,4, Selvester et al. teaches the text and voice messages in col. 24, lines 37-44.

(D) As per claims 5, 6, 24,30, checking the integrity of physiological data (i.e. filtering, pre-processing), extracting patterns and comparing are disclosed in col. 3, line 46, lines 50-53, col. 5, line 17, col. 8, lines 40-50 of Maridossian, and col. 1, lines 58-65, col.2, lines 2-61,col. 5, lines 1-11,col.7, lines 1-7 of Selvester et al.

(E) As per claims 8,9, text message (i.e. text report) and physiological data are displayed in col. 24, lines 36-41, col. 27, lines 30-32 of Selvester et al.

(F) As per claim 10, Mardirossian discloses real time support system for monitoring physiological data comprising:

- a. a library of interpreted physiological data records (i.e., memory 57 for storing a plurality of files or patterns of measured brain activity or responses of particular individuals) (Mardirossian, col. 2, lines 26-31, col. 5, lines 27-31, lines 37-44);
- b. a physiological data acquisition device for gathering sensed physiological signal (Mardirossian, col. 3, lines 41-43, col. 6, lines 34-42); an interpretation module

for interpreting the sensed physiological signal according to predefined criteria to generate an interpretation of the physiological data (Mardirossian, col. 3, lines 46-47; col. 6, line 63 to col. 7, line 15, col. 5, line 58 to col. 6, line 29); and a correlation module (i.e. comparing device) for comparing the interpretation with the physiological data records to determine a set of correlated data records ( i.e., match or close match) (Mardirossian, col. 2, lines 32-35, col. 3, lines 22-23, lines 50-53, col. 8, lines 40-45). Mardirossian fails to explicitly recite the output device. This, however, is disclosed by Selvester et al. Selvester et al. teaches a pictorial display electrocardiographic interpretation system wherein interpretation, predictive interpretation, interpretation at different times T1, T2, etc.. can be presented in static or motion display (Selvester et al. col. 3, lines 17-33, lines 59-65, col. 4, lines 14-23, Figs. 2, 6 a, 6b, 7a,7b, 11a-c,12 a-b,13 a-b,14a-b,15 a-b). It would have been obvious to one having ordinary skill in the art at the time of the invention to include pictorial display system of Selvester et al. into Mardirossian with the motivation of providing a better representational output display with high degree of configurational and other accuracy of certain selected heart conditions. (Selvester et al. col. 1, lines 19- 25, col. 3, lines 60-65).

(G) As per claim 11, display device is disclosed in Selvester et al. col. 3, lines 17-33, lines 59-65, col. 4, lines 14-23, Figs. 2, 6 a, 6b, 7a, 7b, 11a-c,12 a-b,13 a-b,14a-b,15 a-b.

(H) As per claims 12, 15, expert location for receiving transmitted physiological data and communication module are disclosed in col. 2, lines 54-56, col. 3, lines 47-49 of Mardirossian, and col.10, lines 47-54, col. 15, lines 1-9, Fig. 3 of Selvester et al.

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- (I) As per claim 14, Selvester et al teaches an information filter in col. 1, lines 58-61.
- (J) As per claims 16,17, 23, Selvester et al teaches the text and voice messages in col. 4, lines 42-48, col. 24, lines 37-44.
- (K) As per claims 19, 31 libraries of supplemental materials (i.e. word, phrase, thought, subject specific and non-subject specific etc.) are disclosed in col. 2, lines 26-31, col. 5, lines 27-31, lines 37-44, col. 7, lines 40-50 of Mardirossian, and col. 2, lines 15-34, lines 45-61, col. 11, lines 1-6, of Selvester et al, col. 11.
- (L) As per claims 20, 21, Mardirossian teaches that physiological data can be heart signal (Mardirossian, col. 5, line 24). Selvester teaches ECG signal in col. 3, lines 52-65.
- (M) As per claim 25, Mardirossian discloses real time support system and method for monitoring physiological data, comprising the steps for:
  - a. acquiring sensed physiological signal (Mardirossian, col. 3, lines 41-43, col. 6, lines 34-42);
  - b. interpreting the sensed physiological signal according to predefined criteria to generate an interpretation (Mardirossian, col. 3, lines 46-47; col. 6, line 63 to col. 7, line 15, col. 5, line 58 to col. 6, line 29);
  - c. correlating (i.e. comparing) the interpretation with the physiological data records in a library of physiological data records (i.e., memory 57 for storing a plurality of files or patterns of measured brain activity or responses of particular individuals), (Mardirossian, col. 2, lines 26-35, col. 3, lines 22-23, lines 50-53, col. 5, lines 27-31, lines 37-44).

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Mardirossian fails to explicitly recite the step for displaying the interpretation and the correlated physiological records on a display. This, however, is disclosed by Selvester et al. Selvester et al. teaches a pictorial display electrocardiographic interpretation system wherein interpretation, predictive interpretation, interpretation at different times T1, T2, etc.. can be presented in static or motion display (Selvester et al. col. 3, lines 17-33, lines 59-65, col. 4, lines 14-23, Figs. 2, 6 a, 6b, 7a,7b, 11a-c,12 a-b,13 a-b,124a-b, 15 a-b). It would have been obvious to one having ordinary skill in the art at the time of the invention to include pictorial display system of Selvester et al into Mardirossian with the motivation of providing a better representational output display with high degree of configurational and other accuracy of certain selected heart conditions. (Selvester et al. col. 1, lines 19- 25, col. 3, lines 60-65).

(N) As per claim 26, Mardirossian teaches the step for establishing a library of interpreted physiological data records (i.e., memory 57 for storing a plurality of files or patterns of measured brain activity or responses of particular individuals) in col. 2, lines 26-31, col. 5, lines 27-31, lines 37-44.

(O) As per claims 27-29, expert location for receiving transmitted physiological data and communication module are disclosed in col. 2, lines 54-56, col. 3, lines 47-49 of Maridossian, and col.10, lines 47-54, col. 15, lines 1-9, Fig. 3 of Selvester et al. Selvesrer et al. also teaches the text and voice messages in col. 4, lines 42-48, col. 24, lines 37-44. The communication module disclosed by Selvester et al. includes the Internet (col. 10, line 53 of Selvester et al). This meets the "instant" feature in claims 28, 29.

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6: Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mardirossian in view of Selvester et al. as applied to claim 1 above, and further in view of Cairnes (6139494)

(A) As per claim 7. Mardirossian and Selvester et al. fail to recite a library of education material. However, this is well known as evidenced by Cairnes. Cairnes teaches a physiological monitoring device including a library of educational material. See Cairnes, col. 5, lines 30-50, col. 12, lines 18-26. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a library of educational material with the motivation of improving the patient's understanding on therapies and health care issues and therefor facilitating the wellness and preventive care system which serves to prolong life, reduce sickness, and lower the cost for operating hospital and clinic. See col. 12, lines 11-16, lines 35-40 of Cairnes.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mardirossian in view of Selvester et al. as applied to claim 10 above, and further in view of Bardy (6203495).

(A) As per claim 18. Mardirossian and Selvester et al. fail to recite a library located on the server. However, it is well known as evidenced by Bardy. Bardy teaches a physiological monitoring device wherein database of physiological data is located on a server. Bardy, col. 4, lines 15-20. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a server with the motivation of increasing the capacity of the storage device to network level, thereby expanding the application to world wide system. See Bardy, col. 7, lines 1-5.

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8. Claims 13, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mardirossian in view of Selvester et al. as applied to claims 10, 12 above, and further in view of Albert et al. (6264614).

(A) As per claim 13, Mardirossian and Selvester et al. fail to recite a porter. However, this is well known as evidenced by Albert et al.. Albert et al. discloses a heart monitoring system wherein the Internet addressing capability is included. Web site and the Internet connection allow browsing and downloading of information and acquisition application program. See Albert et al. Fig.3, col. 6, lines 45-65. It would have been obvious to one having ordinary skill in the art at the time of the invention to include web site or porter with the motivation of facilitating the operation of the system by providing the ability to access the Internet to browse information and download application programs. See Albert, col. 10, lines 45-65.

(B) As per claim 22, Mardirossian and Selvester et al. fail to a browser. However, it is well known to include browser in physiological monitoring system as evidenced by Albert et al.. Albert et al. teaches a physiological monitoring device that includes web browser . Albert et al., Figs 3,8, col. 10, lines 37-60. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a browser with the motivation of facilitating the operation of the system by providing the ability to navigate and access the Internet to browse information and to download application programs. See Albert, col. 10, lines 45-65.

***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6665559. Although the conflicting claims are not identical, they are not patentably distinct from each other because the previous electrocardiogram of patent 6665559 is a particular type of a library of interpreted physiological data.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Method and system for monitoring the heart" (5966692); "Long term physiological polygraphic recordings" (5047930); "Portable physiological monitoring system" (6083156); "Automated visual function testing via telemedicine" (6027217); "Interactive body implantable medical device" (5549654); "Echocardiography workstation" (6674879); "Continuous monitoring using predictive instrument" (5724983); "Feasibility analysis of a case -based reasoning system for automated detection of coronary heart disease from myocardial scintigrams", Hadad M et al. ;Jan. 1997, Artificial intelligence in medicine, p61-78, Dialog file 155, Acc. no. 13347570, " Problem-knowledge coupling: a tool for physical therapy clinical practice"; Zimmy, Nancy J. et al.; Feb.1989; Magazine/Journal; "Physical Therapy, V69, n2, 9155, Dialog file 149, Account no. 01188658.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim T. Bui whose telephone number is 703-305-5874. The examiner can normally be reached on Monday-Friday from 8:30A.M. to 5:00P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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